

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: August 26, 2009
Electronic Signature for Megan E. Williams: /Megan E. Williams/

Docket No.: BGG-A117CNRCE2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Michele Sanicola-Nadel *et al.*

Patent No.: 7,531,174

Application No.: 10/693,538

Confirmation No.: 4018

Filed: October 23, 2003

Art Unit: 1643

For: CRIPTO BLOCKING ANTIBODIES AND
USES THEREOF

Examiner: Huff, Sheela J.

MS Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO DECISION ON REQUEST FOR RECONSIDERATION OF PATENT
TERM ADJUSTMENT AND NOTICE OF INTENT TO ISSUE CERTIFICATE OF
CORRECTION**

Dear Sir:

1. This statement is respectfully submitted in response to the “Decision on Request for Reconsideration of Patent Term Adjustment and Notice of Intent to Issue a Certificate of Correction” (“Decision”) mailed from the U.S. Patent and Trademark Office, Office of Petitions, on July 27, 2009 for the above-referenced patent. In view of the following, it is respectfully requested that Patentees be granted a Patent Term Adjustment (PTA) of **531 days** for the above-referenced application.

2. The Patent Term Adjustment indicated in the “Certificate of Correction – Draft Copy” enclosed with the Decision is 210 days. This determination of 210 days is in error for the reasons discussed below.

3. The factual bases for the determination of 531 days of PTA are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced patent, Patentees are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance 37 CFR §1.703(a)(1), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (*i.e.*, by December 23, 2004). As shown in the USPTO’s Patent Term Adjustment Calculation Sheet (Exhibit A), the Office failed to mail an action under 35 U.S.C. §132 (a Restriction Requirement) until October 18, 2005. As such, Patentees are entitled to a period of patent term adjustment beginning December 24, 2004 and ending on October 18, 2005, the date of mailing of the Restriction Requirement by the Office.

Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is **299 days**. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office.

(ii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

Patentees respectfully submit that the Office did not comply with the requirement of 35 U.S.C. §154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the patent was filed under 35 U.S.C. §111(a). As indicated on the face of the patent, the instant patent issued on May 12, 2009. As such, there was a delay of 932 days.

However, since the exclusionary period for continued examination set forth in 37 CFR §1.702(b)(1) applies to the instant patent, the number of days in the period beginning on the date on which Patentees first filed a Request for Continued Examination (November 8, 2007) and ending on the issue date of the patent (May 12, 2009), *i.e.*, 552 days, is excluded from the period of Three Years Delay (*i.e.*, 932 days). Therefore, in accordance with 37 CFR §1.703, Patentees have calculated a maximum period of Three Years Delay based on the period of time beginning

on the day after the date that is three years after the date on which the above-referenced patent was filed under 35 U.S.C. § 111(a) (*i.e.*, October 24, 2006), and ending on the date Patentees first filed a Request for Continued Examination (*i.e.*, November 8, 2007). This period of delay is **380 days**.

Patentees note that the Decision issued by the Office of Petitions indicated that the period of Three Years Delay is 381 days, inclusive of either the date that is three years from the date the patent was filed under 35 U.S.C. § 111(a) (*i.e.*, October 23, 2006), or the date that Patentees filed the Request for Continued Examination (*i.e.*, November 8, 2007). Patentees respectfully submit that this calculation is in error for the reasons noted above, and request review of this determination by the Office, as appropriate.

(iii) “4 Month PTO Issue of Patent Delay” Pursuant to 37 CFR § 1.702(a)(4)

The Office did not comply with the requirement of 37 CFR § 1.702(a)(4), which requires issuance of a patent not later than four months after the date on which the issue fee was paid under 35 USC 151 and all outstanding requirements were satisfied. As shown on the Office’s PTA Calculation Sheet (Exhibit A), the Office failed to issue a patent until May 12, 2009. Therefore, Patentees are entitled to a period of patent term adjustment beginning on the day after the date that is 4 months after the date on which the issue fee was paid, *i.e.*, April 20, 2009, and ending on the date the patent issued, *i.e.*, May 12, 2009. Accordingly, the period of patent term adjustment due to the 4-Month Delay by the Office is **23 days**, which is in agreement with the period calculated by the USPTO on the PTA Calculation Sheet (Exhibit A).

(iv) Calculation of Total Period of Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (299 days), the minimum period of Three Years Delay (380 days), and the 4 Month Issue of Patent Delay (23 days), to the extent these periods of delay are not overlapping. As the period of 14 Month Delay ended on October 18, 2005, prior to the first day of the period of Three Years Delay, *i.e.*, October 24, 2006, and the period of Three Years Delay ended on November 8, 2007, prior to the first day of the period of 4 Month Issue of Patent Delay, *i.e.*, April 20, 2009, Patentees submit that these periods are not overlapping. Accordingly, the sum of the total examination delays results in a total period of examination delay of **702 days**.

B. “Applicant Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. As shown in the USPTO’s PTA Calculation Sheet (Exhibit A), the Office has calculated a period of Applicant Delay of 171 days.

(i) Applicant Delay for Filing an Information Disclosure Statement

Patentees respectfully submit that a period of Applicant Delay of **19 days** accrued for the delayed submission of an Information Disclosure Statement (IDS) on February 6, 2006. This IDS was filed without a statement under 37 CFR §1.704(d), 19 days after the filing of a response by Patentees to the Restriction Requirement on January 18, 2006. This period is consistent with the PTA Calculation Sheet (Exhibit A) from the Office. Pursuant to 37 CFR §1.704(c)(8), this 19 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(ii) Applicant Delay for Responding to Non-Final Action Dated March 16, 2006

Patentees respectfully submit that an additional period of Applicant Delay of **61 days** accrued for the delayed submission of an Amendment and Response on August 16, 2006. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 61 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iii) Applicant Delay for Responding to Non-Final Action Dated November 1, 2006

Patentees respectfully submit that an additional period of Applicant Delay of **89 days** accrued for the delayed filing of a Response to Non-Final Action on May 1, 2007. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 89 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iv) Applicant Delay for Responding to Notice of Allowance Dated February 25, 2008

Patentees respectfully submit that an additional period of Applicant Delay of **2 days** accrued for the delayed filing of a Request for Continued Examination and Information Disclosure Statement on May 27, 2008. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 2 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(v) Calculation of the Total Period of Applicant Delay

In view of the above, Patentees have calculated a total period of Applicant Delay of **171 days**, which is the sum of the following Applicant Delays: (i) the 19 day period ; (ii) the 61 day period; (iii) the 89 day period ; and (iv) the 2 day period. Accordingly, Patentees respectfully submit that the period of Applicant Delay is **171 days**. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of Examination Delay reduced by the period of Applicant Delay. Therefore, Patentees submit that the correct patent term adjustment for the above-referenced application is **531 days**, which is the difference between the total period of examination delay (702 days) and the period of Applicant Delay (171 days). This determination is consistent with the interpretation of 35 U.S.C. § 154(b)(1)(B) and 35 U.S.C. § 154(b)(2)(A) established in Wyeth v. Dudas, 580 F.Supp.2d 138 (D.D.C. 2008).

4. Patentees respectfully submit in the alternative that they are entitled to **232 days** of PTA, including 23 days of PTA for the period in excess of four months between payment of the Issue Fee and the date of issuance of the patent (see 3(A)(iii) above), in the event that the USPTO maintains the interpretation of 35 U.S.C. § 154(b)(1)(B) and 35 U.S.C. § 154(b)(2)(A) set forth in the Decision as follows, contrary to the interpretation in Wyeth:

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B),

the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).

(Decision, page 4, first full paragraph, referencing *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004)).

In particular, Patentees direct the attention of the Office to *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004) at paragraph 11, which states, in relevant part:

[D]elays resulting in the Office’s failure to meet the time frames specified in 35 U.S.C. 154(b)(1)(A) (the “fourteen-four-four-four” provisions) are not always overlapping with a delay resulting in the Office’s failure to issue a patent within the three-year time frame specified in 35 U.S.C. 154(b)(1)(B) because not all application pendency time is counted toward this three-year period. *See 35 U.S.C. 154(b)(1)(B)(i)-(iii)....The delay due to the Office’s failure to issue a patent after the issue fee has been paid and all outstanding requirements have been met within the four-month time frame specified in 35 U.S.C. 154(b)(1)(A)(iv) does not “overlap” with the three-year time frame specified in 35 U.S.C. 154(b)(1)(B) because the period subsequent to the filing of the RCE is not included in the three-year time frame specified in 35 U.S.C. 154(b)(1)(B).* (emphasis added)

The Decision from the Office of Petitions indicates that:

381 days is the actual number of days issuance of the patent was delayed. Accordingly, at issuance, the Office should have entered only 59 additional days of patent term adjustment (not 82 days) for the Office taking in excess of three year [sic] to issue the patent for a total Office delay of 381 (299 + 23 + 59) days....In view thereof, the revised determination of patent term adjustment at the time of the issuance of the patent is 210 days (381 days of Office delay – 171 days of applicant delay). (Decision, page 6, paragraphs 1-2).

Patentees submit that the 23 days of delay by the Office for failure to issue a patent within four months of payment of the Issue Fee (“Four Month Delay;” see 3(A)(iii) above) do not overlap with the 381 days of “Three Years delay” beginning on the day after the date that is three years after the filing date of the application and ending on the date of filing of an RCE (see 3(A)(ii) above). Accordingly, the actual number of days issuance of the patent was delayed, applying the USPTO’s interpretation of “overlap” under 35 U.S.C. § 154(b)(2)(A) discussed above, is **404**

days ($381 + 23 = 404$). Subtracting 171 days of Applicant delay (see 3(B)(v) above) results in a determination of **233 days** ($404 - 171 = 233$) of PTA.

While the Office does not explain the origin of their determination of either 59 or 82 days of PTA resulting from Three Years delay, Patentees note that the difference between the 381-day period of “Three Years delay,” the 299-day period of “Fourteen Month Delay,” and the 23-day period of “Four Month Delay” is 59 days ($381 - 299 - 23 = 59$). Accordingly, the Office has erroneously considered the 23-day period of “Four Month Delay” to overlap with the 381-day period of “Three Years delay.” This error resulted in the determination of 210 days of PTA appearing on the “Certificate of Correction – Draft Copy” enclosed with the Decision from the Office of Petitions ($381 - 171 = 210$). In view of the foregoing, Patentees submit that the 210 days of PTA listed on the “Certificate of Correction – Draft Copy” is erroneous, and request that the Certificate of Correction not be entered.

Patentees note for the record that they believe the USPTO’s interpretation of “overlap” under 35 U.S.C. § 154(b)(2)(A) is erroneous to the extent that it contradicts the interpretation set forth in Wyeth v. Dudas, 580 F.Supp.2d 138 (D.D.C. 2008), for the reasons stated above. Moreover, Patentees note that if the period of “Three Years Delay” is calculated as 380 days, rather than 381 days, for the reasons set forth in 3(A)(ii) above, the determination of PTA using the USPTO’s interpretation of “overlap” under 35 U.S.C. § 154(b)(2)(A) is **232 days**, rather than 233 days.

5. In view of the foregoing, it is respectfully requested that this Statement regarding Patent Term Adjustment be favorably considered and that a Certificate of Correction be issued to reflect a patent term adjustment of **531 days**. Notwithstanding, it is respectfully submitted that the Decision of the Office of Petitions to debit Patentees an additional 23 days of Patent Term Adjustment was made in error, for the reasons noted herein. Accordingly, Patentees request reconsideration and reversal of the decision to debit 23 additional days of Patent Term Adjustment from the instant patent, and request that the “Certificate of Correction – Draft Copy” enclosed with the Decision not be entered.

Patentees believe that no fee is due upon submission of this statement. However, if a fee is due, the Office is invited to charge our deposit account number 120080, from which the undersigned is authorized to withdraw.

Dated: August 26, 2009

Respectfully submitted,

By /Megan E. Williams/
 Megan E. Williams
 Registration No.: 43,270
 LAHIVE & COCKFIELD, LLP
 28 State Street
 Boston, Massachusetts 02109
 (617) 227-7400
 (617) 742-4214 (Fax)
 Attorney For Applicant